UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION
Master File No. 2:12-MD-02327
MDL No. 2327
JOSEPH R. GOODWIN U.S. DISTRICT JUDGE
IN RE: ETHICON, INC.
PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION
THIS DOCUMENT RELATES TO:
Sharon Carpenter, et al. v. Ethicon, Inc., et al.
Civil Action No. 2:12-cv-00554

Joy Essman, et al. v. Ethicon, Inc., et al.,
Civil Action No. 2:12-cv-00277

Barbara A. Hill, et al. v. Ethicon, Inc., et al.,
Civil Action No. 2:12-cv-00806

Brenda Riddell, et al. v. Ethicon, Inc., et al.,
Civil Action No. 2:12-cv-00547

Barbara J. Vignos-Ware, et al. v. Ethicon, Inc., et al.,
Civil Action No. 2:12-cv-00761
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RALPH ZIPPER, M.D., FACOG, FPMRS
March 20, 2016

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Deposition of RALPH ZIPPER, M.D., FACOG, FPMRS, held at Hilton Rialto Place, 200 Rialto Place, Melbourne, Florida, commencing at 9:26 a.m., on the above date before Rhonda Hall-Breuwet, RDR, CRR, LCR, CCR, FPR, CLR, NCRA Realtime Systems Administrator

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I N D E X

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abdominally because it's a mesh that was readily available in hospitals, and because of that, the likelihood is high that I used it. I just can't recall.

Q. Okay. That's fine. And do you remember -- maybe I should back up.

Do you remember when you first used any type of polypropylene mesh, be it self-tailored or in a Y shape, for abdominal repair of pelvic organ prolapse?

MR. THORNBURGH: Objection.

THE WITNESS: I don't recall the material that we were using in residency. There is certainly a good chance it was polypropylene mesh, which would put us into the mid to late 1990s. 1994, '95, '96.

BY MR. TOMASELLI:

Q. Okay. Do you still use polypropylene mesh today for abdominal repair of pelvic organ prolapse?

MR. THORNBURGH: Objection.

THE WITNESS: I do.

BY MR. TOMASELLI:

Q. All right. And my understanding is that you use a product called Alyte Y?

A. Yes.

Q. Are there other products that are manufactured for the use of abdominal repair of pelvic organ prolapse?

MR. THORNBURGH: Objection.

BY MR. TOMASELLI:

Q. Maybe that was a terrible question. Let me try again. Withdrawn.

Alyte Y is a mesh that's manufactured for use in abdominal repair of pelvic organ prolapse; is that correct?

A. Yes.

Q. Are there other mesh -- polypropylene meshes that you have used other than Alyte Y for the abdominal repair of pelvic organ prolapse?

A. Yes, but I couldn't tell you

those brands today.

Q. Okay. I know that from just searching another -- well, withdrawn.

Have you ever used a mesh Y polypropylene product called IntePro?

A. I don't recall.

Q. Fair enough. You still -- I may have asked this already and I apologize, but you still use polypropylene mesh for the use of abdominal --

A. Sacrocolpopexy.

Q. -- sacrocolpopexy for the treatment of pelvic organ prolapse today?

MR. THORNBURGH: Objection.

THE WITNESS: Yes.

BY MR. TOMASELLI:

Q. All right. And the mesh that you use is still the Alyte Y?

MR. THORNBURGH: Objection.

THE WITNESS: Yes.

BY MR. TOMASELLI:

Q. My understanding is that the ASC, I'll call it -- is that okay for the

abdominal sacrocolpopexy?

A. Sure.

Q. All right. My understanding is that ASC can be performed openly, laparoscopically, or robotically; is that right?

A. Correct.

Q. All right. When did you start using -- well, withdrawn.

My understanding today is that you use robotic ASC?

A. I use all approaches.

Q. All approaches. Okay. Can you best estimate for me when you started using robotic ASC?

A. No.

Q. Do you remember the first time that you used robotic ASC?

A. I remember the experience. I don't remember the date.

Q. Okay. Do you -- that's fair.

Do you remember whether it was in the last year or two, or could we

THE WITNESS: Yeah.
BY MR. TOMASELLI:
Q. It says in the late -- it says, "The late 1990s marks the time when an elite group of expert urogynecologists began to gain experience with the transvaginal implantation of polypropylene mesh in the treatment of pelvic organ prolapse."
Do you see where I am?
A. Yes, I do.
Q. All right. Now, where did you come up with that information? How did you learn that?
A. By being what device companies have described and called me to be, a key opinion leader, I intermingled with other key opinion leaders and elite surgeons throughout the country and were aware of what was being done with self-tailored mesh.
Q. And when you talk about an elite group of urogynecologists being --
A. I'm sorry. "Elite" may be

too ambiguous and too colorful of a word, but I also called them key opinion leaders as identified by device companies. I think that would be a better description.
Q. All right. So instead of your report reading that an elite group of expert urogynecologists began to gain experience, you would rather say that a group of key opinion leaders identified by device companies?
A. I think that that would be a more precise term. "Elite" is not inaccurate; it's just not as precise.
Q. All right. Well, this group of gynecologists that are expert or elite, do you recall who you're thinking about in terms of these people, like their names?
A. Offhand, I remember --
MR. THORNBURGH: Objection.
THE WITNESS: -- that Dr. Kohli was doing -- placing self-tailored mesh. I believe

that Dr. Ross was doing a little bit. He may have been doing more animal tissue, more allograft tissue. I believe that --
BY MR. TOMASELLI:
Q. So I'm talking about the polypropylene mesh here.
A. Yeah, so am I.
Q. Okay.
MR. THORNBURGH: He's answering your --
THE WITNESS: I believe at that time Dr. Garely may have been. Dr. Miklos may have been. Dr. Lucente may have been. I actually -- I, to a lesser degree, recall exact names. It's just as an overall growing trend among that basic body of experts.
BY MR. TOMASELLI:
Q. All right. And this self-tailored mesh was indeed placed through the vagina?
A. Yes.

Q. Okay. By the mid-2000s, do you know if this group of expert gynecologists stopped using mesh via the transvaginal route?
MR. THORNBURGH: Objection.
THE WITNESS: You're talking about the self-tailored mesh or are you talking about kits with arms?
BY MR. TOMASELLI:
Q. I guess I'm just talking about your statement here that in the late 1990s, the -- this expert group began to use transvaginal mesh. And my question was, do you know when they stopped?
A. No.
Q. I think you wrote -- and I don't remember where -- but I believe you stated that the highest level of scientific evidence is the randomized clinical trial; is that right?
A. No. I've stated the highest level of evidence is the meta-analysis of

multiple randomized control trials.
Q. Okay. Fair enough.
So below a systematic review or meta-analysis of a group of randomized trials, below that would be the single randomized trial?
MR. THORNBURGH: Objection.
THE WITNESS: Yes.
Are we on Prolift right now?
BY MR. TOMASELLI:
Q. Yes.
A. Okay.
(Exhibit Number 11, Article Titled "Vaginal repair with mesh versus colporrhaphy for prolapse: a randomised controlled trial," by Carey, et al., was marked for identification.)
BY MR. TOMASELLI:
Q. Doctor, I'm handing you what I've marked as Deposition Exhibit Number 11, and is that a --
A. This is Prosima, I believe, sir.

MR. THORNBURGH: This is Dr. Carey.
THE WITNESS: Prosima. That's okay. I just asked you if it was Prolift and you said yes. But I know there's a lot of information today. Okay. Let's talk about this.
This is a paper accepted in 2009 and published in 2009 by Dr. Carey, the inventor of the Prosima procedure, by Dr. Carey, who received a million dollars for signing over a license of the Prosima intellectual property to Ethicon, and who had a deal for, I believe, 2-1/2 percent of downstream revenues worth up to $6 million a year based on Ethicon's projections.
And this is a randomized controlled trial of which Dr. Carey is the principal author, the lead author, published in

2009, comparing, I believe, combined anterior and posterior Prosima to combined native tissue anterior and posterior repair.
BY MR. TOMASELLI:
Q. This Deposition Exhibit Number 11 --
MR. THORNBURGH: Does that answer your question?
BY MR. TOMASELLI:
Q. Is Deposition Exhibit Number 11 a randomized trial published by Dr. Carey in 2009?
MR. THORNBURGH: Objection.
THE WITNESS: Yes. It's a randomized controlled trial. The control group was a native tissue plication. The experimental group was anterior and posterior Prosima combined with native tissue.
BY MR. TOMASELLI:
Q. Okay. I thought that this mesh that was used in Carey 2009 was Gynemesh PS.

A. It is Gynemesh PS, as you pointed out earlier, and I responded. I said the same defective mesh which Ethicon has demonstrated in its numerous animal studies to be defective, which subsequent investigators such as Liang and Feola have further validated to be defective compared to alternative meshes, exist in both the Prosima and the Prolift, with the key difference that in the Prolift, it gets dragged through muscle bodies, encouraging extrapelvic complications and worsening complications through inflammation and infection and contraction in the muscle bodies with associated degradation.
This here is a study using the Prosima device composed of Gynemesh PS with the Carey method, licensed by Dr. Carey to Ethicon for a million dollars, and a potential for six-plus million dollars in downstream revenue every year based on Ethicon projections, and biased. As you asked me earlier, did

I feel that the owner of a patent could in an unbiased way evaluate a study on their IP, and I said no, and here is Dr. Carey.

Q. Was this study peer-reviewed?

A. I believe the British Journal of Obstetrics and Gynaecology is peer-reviewed. I do recall that there was a problem -- no, it was the study before that was at first rejected.

I believe this was the study where Dr. Carey was unable to show any significant benefit of Prosima compared to native tissue surgery, and also found either a 16 or 17 percent incidence of de novo dyspareunia associated with Prosima, although he did find a mesh extrusion rate which was lower than Prolift.

Q. Dr. Zipper, I'm going to take you through some of that data. If you can just maybe concentrate on my simple question every now and again, I certainly would hugely appreciate it.

A. I will certainly do my best to apply Occam's razor whenever possible. However, these are not -- even though the questions may appear simple, the answers are not simple.

Q. Okay. I thought my simple question was, is this paper or was it peer-reviewed.

A. And I answered it. I said yes.

Q. Okay. Were patients enrolled in this study between February 2003 and August 2005?

A. I'd have to read the study to refresh my memory with regard to the enrollment time frame.

Q. If you'd turn to the second page under methods, the end of the first paragraph, do you see that it states that patients were enrolled from February 2003 to August 2005?

A. You said second page? Page number 1381?

Q. Yes, sir.

A. And the end of the second paragraph?

Q. End of the first paragraph under "Methods."

A. Yes. I see that. "All eligible women who agreed to participate in this study and provided written informed consent were enrolled between . . . 2003 and August 2005." Yes, I see that.

Q. Can you confirm that in this study by Carey published in 2009 that the patients were enrolled between February 2003 and August 2005?

MR. THORNBURGH: Objection. Joe, it's the same exact question you just asked.

MR. TOMASELLI: I think the answer is just simply yes.

MR. THORNBURGH: He said -- he says yes.

BY MR. TOMASELLI:

Q. Okay. So we can agree it's yes?

MR. THORNBURGH: Well, I'm not going to answer for him. I'm just telling you it's the same question.

THE WITNESS: I would say the "Methods" section of this paper says eligible patients were enrolled between February of 2003 and 2005. It doesn't say when they were treated.

BY MR. TOMASELLI:

Q. Okay.

A. But we know from Ethicon internal documents that this data was available well before publication.

Q. Dr. Zipper, if you'll turn to Table 2 of the paper, which is on page 1383.

Do you see that?

A. Sure.

Q. The top comparison in Table 2 is, I think, a comparison that you referenced earlier which is whether there was objective success proven in this

study comparing Gynemesh PS to native tissue surgery.

Do you see that?

A. Actually, that's not what this study did. That's a misrepresentation of the study.

Q. All right.

A. This study compared -- sir, this study compared the Prosima device in the form which was -- included Gynemesh PS used with an unvalidated type of vaginal splint combining a semi-rigid pessary with a balloon, combined with native tissue surgery, to native tissue surgery in a randomized controlled fashion.

Q. Okay. In terms of the study that we have in front of us by Carey -- published by Carey in 2009.

A. Hang on. I want to back up. I misstated something. This study, although it was on the Carey method, which included a vaginal splint and a balloon, for some reason the Prosima

vaginal splint and balloon were excluded from this study.

So this study actually randomized patients to the Prosima device made of Gynemesh PS with some unique features, combined with native tissue plication, to native tissue plication. Okay. So back to this chart.

Q. Okay. In terms of the objective success in Table 2, do you see that under the mesh portion the authors report an 81 percent success rate? It's just the first line, Doctor.

A. I understand that.

Yes. I'm looking at the first line where it says that there is no significant difference between the mesh group and the no-mesh group.

Q. Right. And I'm -- that's exactly where I intend to head, so maybe we can just take it step by step. Okay, Doctor?

Is it true that the authors report an 81 percent success rate in the

mesh group in the first line for objective success?

MR. THORNBURGH: Objection.

THE WITNESS: I'm going to answer that with a yes or no, which is what I think you want. However --

BY MR. TOMASELLI:

Q. And then I'm going to ask you about the no mesh, and then I'm going to ask you about the P-value and what it means. Okay?

A. But if we're going to look at trends rather than significant values, it's going to end up very, very poorly, much worse for Prolift, because the trends for Prosima and Prolift perform so much worse. Those numbers are so much worse than the Cochran data, and so I suggest we stay with significant numbers rather than trends, but fine.

Q. No, that's fine. I'm going to.

A. All right. So --

Q. I promise you, Doctor. That's where I'm headed.

A. So it shows 51 out of 63 women had a POP-Q stage of 0 or 1.

Q. Okay. And then in terms of the no-mesh group, it was -- objective success was measured in 40 of 61, or approximately 66 percent, of the patients, correct?

A. Yes.

Q. And the P-value that's reported for this comparison is 0.07.

Do you see that, sir?

A. Yes.

Q. And P-values are the results of testing to see if you can reject the null hypothesis that the treatments are the same, correct?

MR. THORNBURGH: Objection.

THE WITNESS: Occur by chance.

BY MR. TOMASELLI:

Q. So if the P-value -- well, withdrawn.

In medicine, it's generally accepted that the P-value of .05 is the cutoff for significance?
A. Right.
Q. All right. And so if a P-value is greater than .05, the treatments --
A. Are the same.
Q. -- are the same.
There's -- even though there may be numerical differences, you cannot say that they're actually different?
A. Right. So a P-value of .06 or .05 -- .051 is the same as a P-value of .8.
Q. Fair enough.
A. They're both not significant.
Q. Fair enough.
And then if we have a P-value that is .049 or below, we in science and medicine would say, "Okay. We can" -- "we can reject the null and say that those numbers are actually

different."
MR. THORNBURGH: Objection.
BY MR. TOMASELLI:
Q. Is that right?
MR. THORNBURGH: Objection.
THE WITNESS: Yes.
BY MR. TOMASELLI:
Q. Okay. And so from a medical and statistical perspective here, we cannot say that Gynemesh PS was superior to no mesh, the no-mesh group?
A. Correct.
Q. And if you turn with me to the "Discussion" section, which is one page over -- do you see where in the left-hand column there's a big word "Discussion"?
A. Yes.
Q. All right. And the first sentence of the discussion says -- the authors state, "Our results failed to demonstrate that vaginal repair surgery augmented by mesh was significantly more successful in terms of reduced recurrent

prolapse than traditional colporrhaphy 12 months following surgery."
Do you see that?
A. Yes.
Q. So the authors themselves admit that their results are not significant, right?
A. Yes.
MR. THORNBURGH: In 2009. Sorry.
BY MR. TOMASELLI:
Q. In --
A. Yet they continued to sell it.
Q. In terms of the discussion right above the word "Discussion" on the same page, do you see that there's some typewritten portion of the page, again just above the discussion?
A. Okay.
Q. All right. About halfway down there's a -- there's a sentence that starts, "De novo dyspareunia."
Do you see that?

A. Yes.
Q. And it reads, "De novo dyspareunia was reported by five of 18 (27.8%) sexually active women without preoperative dyspareunia in the mesh group and five of 12 (41.7%) in the no-mesh group at 12 months," with a P-value of 0.46.
Do you see that?
A. Yes, I do.
Q. All right. So, again, while the untrained eye might say that there was less de novo dyspareunia in the mesh group than in the no-mesh group, we cannot say that those -- that there was actually less de novo dyspareunia in the mesh group because the P-value is above .5 -- .05, right?
MR. THORNBURGH: Objection.
THE WITNESS: So to the untrained eye, this report from an author who got a million dollars for this method, plus up to $6 million a year, shows that

there is no significance in dyspareunia, even though the untrained eye might think there is based on the percentages reported, yes.

BY MR. TOMASELLI:

Q. So in this study, this Carey 2009 study, you would agree that the rate of de novo dyspareunia at 12 months was no different between the mesh group and the no-mesh group?

MR. THORNBURGH: Objection.

THE WITNESS: In this study by Dr. Carey, who is substantially and magnificently financially biased, I would not agree with your statement, but I would change that statement to state that Dr. Carey did not show or -- sorry -- Dr. Carey -- Dr. Carey's study on a portion of the Prosima method, a modification of the Prosima method, which excluded the novel vaginal splint and balloon

and combined the native tissue surgery with the Prosima shaped mesh and often sutured to the sacrospinous ligament, was not -- did not cause significantly more dyspareunia than the native tissue surgery alone at 12 months.

BY MR. TOMASELLI:

Q. And I'm just trying to understand how to -- you and I are talking about data and data interpretation in the same way. And I'm just trying to make the point or see if you agree that even though the number of de novo dyspareunia of 28 percent in the mesh group is numerically lower than the de novo dyspareunia rate of 42 percent in the no-mesh group, we would agree that you cannot say those rates are different because the resulting test is not significant.

Is what I said correct?

A. I am comfortable stating that the reported results are not

statistically significant.

Q. All right. So in this study, the two things that we've talked about so far in terms of anatomic success rate and in terms of de novo dyspareunia, there was no significant difference between the groups?

MR. THORNBURGH: Objection.

THE WITNESS: In this study, combining a modification of the Prosima method, a modification that was not marketed but did use the Gynemesh PS, the author found a almost 30 percent incidence of de novo dyspareunia, which was not statistically different than what they found from the native tissue group.

BY MR. TOMASELLI:

Q. And what they found in the native tissue group was a rate of almost 42 percent, correct?

MR. THORNBURGH: Objection.

THE WITNESS: A rate that I

don't think was ever duplicated by a nonfinancially incentivized author.

BY MR. TOMASELLI:

Q. Is what I said correct?

A. What both of us said is correct.

And as we stated earlier -- and I think this -- I don't want to beat this horse to death because we've covered it already, but when we compare complications of mesh to native tissue surgery, we're not comparing apples to apples. So dyspareunia with mesh is very different than dyspareunia with native tissue surgery. One is transient and, where not transient, very treatable. The other is not transient, often continues in perpetuity, and often impossible to treat.

Exhibit Number 12 that you have just handed me, "Vaginal Mesh For Prolapse," is a study by Iglesia.

Q. Hold on. Hold on. Doctor,

this is question-and-answer session. Okay? So I don't think there was a question pending to the last statement. But --

A. Am I not allowed to talk if there's not a question?

Q. I think you're -- I think the process is you're supposed to answer my questions.

A. I'll certainly answer your questions, but I don't think I'm not allowed to talk.

Q. No, you can talk.

A. Okay.

Q. I'm certainly not prohibiting that. Withdrawn.

(Exhibit Number 12, Article Titled "Vaginal Mesh for Prolapse, A Randomized Controlled Trial," by Iglesia, et al., was marked for identification.)

BY MR. TOMASELLI:

Q. Dr. Zipper, what I've handed you as Deposition Exhibit Number 12 is a

study by Iglesia and others that was published in 2010.

Do you see that?

A. Yes.

Q. Is this a randomized controlled trial of Prolift versus a native tissue repair?

A. Yes.

Q. Was it peer-reviewed?

A. Yes. I think this is the study that the mesh group was -- stopped enrolling prematurely because of excessive complications.

Q. It was stopped prematurely because five people had mesh exposure.

Do you remember that?

MR. THORNBURGH: Objection.

THE WITNESS: Actually, sir, no disrespect for you, but I am a surgeon who reads and reviews peer-reviewed medical journals all the time, and this study had a predetermined stopping point if the mesh extrusion rate, a type of

complication, exceeded 15 percent, a percentage number -- not a number of patients but a percentage number -- they would stop enrolling in that group because of the excess complications.

They exceeded that number, and they stopped enrolling. So they exceeded the predetermined rate of mesh extrusions which they felt would be inappropriate to -- they felt would be inappropriate to continue if mesh extrusions were beyond that number. They exceeded that number, and they stopped enrolling.

BY MR. TOMASELLI:

Q. Okay. Dr. Zipper, can you turn to page 298 of that Exhibit 12.

A. Sure.

Q. Tell me when you're there.

A. I'm there.

Q. All right. You quoted a --

an erosion rate of 15.6 percent. Can you look at the bottom right-hand column of that page.

A. I actually said 15 percent.

Q. Okay. The bottom right-hand column of the page, do you see where there's a paragraph that starts with, "Of the 32 mesh patients"?

A. Correct.

Q. And it says "five developed erosions," right?

A. Correct.

Q. So when I said five, I was actually trying to be completely honest and truthful with you. Okay?

MR. THORNBURGH: Objection.

BY MR. TOMASELLI:

Q. Do you understand that?

MR. THORNBURGH: Objection.

THE WITNESS: No, I do not.

MR. THORNBURGH: Argumentative.

THE WITNESS: I don't understand that, sir.

///

BY MR. TOMASELLI:
Q. Okay.
A. I mean this predetermined maximum amount of tolerable extrusions in this study, according to the study protocol, was not a number. It was a percentage. They exceeded the percentage. And interestingly enough, this percentage of extrusions is only a small percentage compared to what they found in the US TVM study.
Q. All right. Is this -- I can't remember if I asked you this. Was this paper peer-reviewed?
A. Yes.
Q. All right.
(Exhibit Number 13, Article Titled "Development of de novo prolapse in untreated vaginal compartments after prolapse repair with and without mesh: a secondary analysis of a randomised controlled trial," by Withagen, et al., was marked for

identification.)
BY MR. TOMASELLI:
Q. I've marked as Deposition Exhibit Number 13 a study by Withagen and others.
MR. THORNBURGH: Withagen, right?
BY MR. TOMASELLI:
Q. Withagen? Is that how you say it?
A. Yes.
Q. Sorry. I apologize to both of you.
MR. THORNBURGH: I get it wrong.
THE WITNESS: I say Withagen.
BY MR. TOMASELLI:
Q. Very sorry. I don't mean to --
A. No disrespect to Withagen.
Q. I don't mean to make this confusing at all to you if I said the name wrong.

A. We're not confused.
Q. All right. Withdrawn.
Dr. Zipper, I've handed you what I've marked as Deposition Exhibit 13, and it's a study by Withagen and others that was published in 2011, correct?
A. No. I don't think. I think it was accepted in October of 2011. I don't recall when it was published. I think that's not -- probably not relevant to the discussion.
Q. Okay. Well --
A. It was published 2012.
Q. All right. In paper form, the part I handed you is -- has a 2012 copyright on it, okay?
A. I believe if you look at the journal date, it's British Journal of Obstetrics and Gynaecology, 2012;119:254-360.
Q. Dr. Zipper, was this Withagen study a randomized controlled trial comparing Prolift to a native

tissue repair?
MR. THORNBURGH: Objection.
THE WITNESS: Yes. This was in a --
MR. THORNBURGH: Go ahead.
BY MR. TOMASELLI:
Q. Is that just a yes?
A. This is an ongoing study started years earlier. There were several other publications on this patient group. And yes, this is a randomized controlled trial which showed a dramatically increased rate of untreated compartment failure compared to native tissue.
Q. All right. I didn't ask you anything about untreated compartment failure or anything like that.
A. It's the title of the article.
Q. Oh, well, then I gave you the wrong one. Fair point.
A. This showed almost over 50 percent untreated compartment failure

rate and which was almost threefold data associated with native tissue repair.

Q. All right. Well, since we're on it -- I pulled out the wrong one. I apologize, Doctor. I thought I had the randomized trial. But this is the 2012 paper. It is a randomized trial?

A. This is -- they started this study a few years earlier, and they continued to report on this study. They used the same group of patients, I believe, to report on the risk factors for erosion. You probably have that paper as well.

Q. Dr. Zipper, this patient -- or this paper reports on untreated compartment failure. I don't know if you noticed this or not, but did you notice that if a apical repair was done as well that there was no untreated compartment failure?

MR. THORNBURGH: Objection.

THE WITNESS: Please let me

respond to this in the entirety. I know that's not a question that can be answered just with a yes or no, although you would like it.

Yes. Ethicon was acutely aware, and being made aware by Withagen and other thought leaders, that the product was defective at the level of the apex. It had been discussed by Dr. Raders, by Dr. Mendelovici, by Dr. -- I believe Dr. Moricky, I think by Dr. Lucente, that the device was failing at the apex, and the device needed to be modified to protect the apex and prevent recurrence in the untreated apex and even the posterior compartment.

And this is validated by Withagen, who points out if you fix this apical problem, this defect in the product, we may not get as much apical failure and

untreated compartment failure.

(Exhibit Number 14, Article Titled "Trocar-Guided Mesh Compared With Conventional Vaginal Repair in Recurrent Prolapse, a Randomized Controlled Trial," by Withagen, et al., was marked for identification.)

BY MR. TOMASELLI:

Q. Dr. Zipper, what I've handed you and I've marked as Deposition Exhibit Number 14 is another paper by Withagen.

MR. THORNBURGH: Do you have a copy for me?

MR. TOMASELLI: Yeah. I handed it right there.

THE WITNESS: Yes.

BY MR. TOMASELLI:

Q. And can you confirm that this is a randomized trial with Prolift compared to native repair that was published in 2011?

A. Yes.

Q. All right. And was this

peer-reviewed?

A. Yes.

MR. THORNBURGH: Is that the only question about this, about Exhibit 14?

MR. TOMASELLI: For now.

(Exhibit Number 15, Article Titled "Laparoscopic sacral colpopexy versus total vaginal mesh for vaginal vault prolapse: a randomized trial," by Maher, et al., was marked for identification.)

BY MR. TOMASELLI:

Q. Doctor, I've handed you what I've marked as Deposition Exhibit Number 15, which is a study by Maher and others.

Do you see that?

A. Yes.

Q. Can you confirm that this is a randomized clinical trial comparing Prolift to native repairs?

MR. THORNBURGH: Objection.

THE WITNESS: I can confirm that this is a randomized controlled trial, without reading the article, based on my memory, comparing laparoscopic sacrocolpopexy to a total Prolift.

BY MR. TOMASELLI:

Q. All right. And this was likewise published in 2011, correct?

A. Yes.

Q. And it's peer-reviewed?

A. Yes. This is the one that showed significantly higher efficacy of the laparoscopic sacrocolpopexy compared to Prolift with higher complication rates associated with the Prolift to also show the Prolift to be associated with vaginal shortening, where the sacrocolpopexy wasn't.

Are we going to talk about this paper?

Q. Can you confirm that this Maher paper that you just told me was -- anatomic success was better with

laparoscopic than Prolift?

A. All success measures were better with laparoscopic compared to Prolift, subjective and objective.

Q. Quality of life measures as well?

A. I can't remember. It was just several symptoms or quality of life, but certainly it was symptomatic benefit and anatomic benefit that was significantly better with the laparoscopic procedure than the vaginal -- than the total Prolift. Total Prolift was also associated with significant vaginal shortening, whereas the laparoscopic procedure was not.

Prolift was associated with approximately -- I'm just going off memory -- 77 -- I think 77 percent efficacy. I believe the total vaginal mesh was -- the Prolift was around 43 percent efficacy based upon objective measures.

There was subjective benefit

of the laparoscopic procedure compared to the total Prolift, and once again, significant vaginal shortening was noted in the total Prolift, yet none was noted in the laparoscopic surgery.

There was also more blood loss, longer hospital stay, longer return to normal activity associated with the total vaginal mesh compared to Prolift.

Sorry, but, I mean, these studies are all really important studies in peer-reviewed journals that time and time again show that show not only is the Prolift -- Prolift product defective, not as good as alternatives, but just also demonstrates that there's a heightened level of awareness of these defects.

Q. Can you turn to Table 5, Doctor, in this paper.

A. You'd rather look at the table rather than the overall outcome?

Q. Table 5.

A. I'm getting there. Table 4. Table 5. Sure.

Q. Do you see that it has quality of life outcomes in this paper?

A. Yes.

Q. Did you previously state to me that there was a significant difference between the groups in terms of quality of life?

A. No, sir.

MR. THORNBURGH: Objection.

THE WITNESS: Absolutely not. Please don't misstate my testimony.

BY MR. TOMASELLI:

Q. I'm asking. I just asked you. Did you tell me --

A. And a minute ago you asked me that, and I said subjective. I said I didn't recall the quality of life statistical analysis. I didn't use the word "statistical." I said I believe that it showed there was a subjective benefit. I didn't testify that there was a quality of life benefit.

I'm going to go back through

and have -- and look through this to read my testimony.
Q. Can you confirm with me right now, looking at Table 5, that there was no significant difference in quality of life between the patients randomized to Prolift and the patients randomized to laparoscopic surgery?
A. Joe, I can do better than that. We can look at the Cochran data, the highest level of evidence, and the overall pool of evidence.
Prolift and transvaginal mesh has never been shown to provide any benefit in quality of life over traditional surgery, yet it has substantially higher complication rates. That's why we're here today. Never been shown to have any quality of life benefits.
MR. THORNBURGH: Are we done with Exhibit 15?
MR. TOMASELLI: For now.
THE WITNESS: Rhonda, if you

need me to go over some of this with you later. I'm sorry.
MR. THORNBURGH: She's good. I'm watching her. She's on it.
(Exhibit Number 16, Article Titled "Anterior Colporrhaphy versus Transvaginal Mesh for Pelvic-Organ Prolapse," by Altman, et al., was marked for identification.)
BY MR. TOMASELLI:
Q. Dr. Zipper, I'm handing you what I've marked as Deposition Exhibit Number 16.
MR. THORNBURGH: The Altman study?
MR. TOMASELLI: Yes.
THE WITNESS: This was excluded. There are only two studies I'm aware of that have ever shown any subjective benefit compared to native tissue, Altman and da Silveira.
And this is the one where

Altman got in a bit of a bind because Altman doesn't disclose his relationship to Ethicon. The New England Journal got involved. Ethicon asked Withagen -- and it's in the internal documents -- to not report -- Ethicon had a right to review this publication and its manuscript before it was published. And Ethicon asked Dr. Withagen to hold back the dyspareunia data, which he did.
And I believe this is it.
Let me see. Yes. This is that Altman study.
BY MR. TOMASELLI:
Q. Dr. Zipper, can you confirm that Deposition Exhibit Number 16 is the study by Altman and others reported in the New England Journal in 2011?
MR. THORNBURGH: Objection.
THE WITNESS: Yes.
BY MR. TOMASELLI:
Q. Was this study

peer-reviewed?
A. Yes.
Q. Was Deposition Exhibit Number 16 a randomized trial between Prolift and native repair?
MR. THORNBURGH: Objection.
MR. TOMASELLI: I don't understand the objection to that.
THE WITNESS: Remember earlier when we talked about trends versus --
MR. THORNBURGH: Doesn't mean it's -- you want to know the objection?
MR. TOMASELLI: No, I don't.
MR. THORNBURGH: Because you asked me for it, and I'll tell you the objection.
MR. TOMASELLI: I said I don't know what it is.
MR. THORNBURGH: Well, do you want to know what it is?
MR. TOMASELLI: I don't.
///

BY MR. TOMASELLI:
Q. Dr. Zipper, here's my question to you: Is Exhibit Number 16 the Altman study published in the New England Journal in 2011, is that a randomized trial between Prolift and a native repair?
MR. THORNBURGH: Objection.
THE WITNESS: This is the -- I believe this is the randomized trial that showed Prolift to have triple the dyspareunia rate, higher blood loss, higher operative time, performed by unblinded Nordic surgeons, by a surgeon affiliated with Ethicon. And I believe it was randomized.
BY MR. TOMASELLI:
Q. In terms of the dyspareunia that you just mentioned to me, was that a significant difference between the groups?
A. It was a trend, which you are so fond of talking about today.

Q. I'm actually not.
A. You want -- another study, you wanted to point out all the trends that didn't reach statistical significance, and I warned you about -- I said we were going to do that for everything then.
Q. I was actually trying to -- just to get an agreement on what statistical significance was.
MR. THORNBURGH: Objection.
BY MR. TOMASELLI:
Q. I don't know how you can --
A. You kept on asking me -- you're pointing out the trends. These numbers are very different, but they're not statistically significant. Once again, the study shows triple the dyspareunia rate -- approximately triple the dyspareunia rate associated with Prolift compared to native tissue surgery.
It did not reach statistical significance.

Q. All right. Did not?
A. Did not.
(Exhibit Number 17, Correction to the Article Titled "Anterior Colporrhaphy versus Transvaginal Mesh for Pelvic-Organ Prolapse," Bates-stamped DEFT 2295k.1, was marked for identification.)
BY MR. TOMASELLI:
Q. Deposition Exhibit Number 17 that I'm handing you is a short publication from the New England Journal pertaining to the Altman study; is that correct?
A. Yes.
Q. Have you reviewed this before?
A. Yes.
Q. Did this correction in the New England Journal change any of the actual numbers that were reported in the Altman 2011 paper?
A. It just changed the meaning

of those numbers.
Q. But it did not change the actual data?
MR. THORNBURGH: Objection. Asked and answered.
THE WITNESS: It just changed the meaning of those numbers.
(Exhibit Number 18, Article Titled "One-year objection and functional outcomes of a randomized clinical trial of vaginal mesh for prolapse," by Sokol, et al., was marked for identification.)
BY MR. TOMASELLI:
Q. Doctor, I'm handing you what I've marked as Deposition Exhibit Number 18, and it's a study by --
A. This is the follow-up of the Iglesia study.
Q. It's a study by Sokol -- withdrawn.
Dr. Zipper, I'm handing you

what I've marked as Deposition Exhibit Number 18, which is a study by Sokol and others published in 2012.

Do you see that?

A. I believe this is the follow-up on the Iglesia study in the American Journal of Obstetrics and Gynecology, 2012, that showed a 15 or 16 percent reoperation rate with the -- with a Prolift and a 0 percent reoperation rate for native tissue surgery.

Q. Is this a randomized -- is Deposition Exhibit Number 18 a randomized trial between Prolift and native tissue repair?

A. It is.

Q. Has it been peer-reviewed?

A. Yes, it has.

(Exhibit Number 19, Article Titled "A Multicenter, randomized, prospective, controlled study comparing sacrospinous fixation and transvaginal mesh in the

treatment of posthysterectomy vaginal vault prolapse," by Halaska, et al., Bates-stamped DX30554-R.1 — DX30554-R.7, was marked for identification.)

BY MR. TOMASELLI:

Q. Doctor, I'm handing you what I've marked as Deposition Exhibit Number 19.

A. Joe, can I take ten seconds to answer a text?

MR. TOMASELLI: No problem. Why don't we go off the record.

THE WITNESS: Thanks.

(Off the record from 12:34 p.m. to 12:34 p.m.)

MR. TOMASELLI: Back on.

BY MR. TOMASELLI:

Q. Dr. Zipper, are you ready to go back on the record?

A. Indeed. Yes.

Q. Okay. Great. I've just handed you Deposition Exhibit Number 19, which is --

MR. THORNBURGH: It's the same thing? I think I got it twice for some reason. Did you mean to do that? Do I have your notes maybe?

MR. TOMASELLI: If you don't want it, you can hand it back. Withdrawn.

BY MR. TOMASELLI:

Q. Dr. Zipper, I've handed you Deposition Exhibit Number 19, which is a paper that was published by Halaska and colleagues in 2012, I believe; is that correct?

A. Yes.

Q. Is this also a randomized trial between Prolift and a native repair?

MR. THORNBURGH: Objection.

THE WITNESS: Yes.

BY MR. TOMASELLI:

Q. Has it been peer-reviewed, sir?

A. Yes.

(Exhibit Number 20, Article Titled "Anterior colporrhaphy versus repair with mesh for anterior vaginal wall prolapse: a comparative clinical study," by El-Nazer, et al., was marked for identification.)

BY MR. TOMASELLI:

Q. Doctor, I'm handing you what I've marked as Deposition Exhibit Number 20, which is a paper by El-Nazer, E-L, dash, N-A-Z-E-R, published in 2012.

Do you see that?

A. Yes.

Q. Are you familiar with this paper?

A. I am. It's been a while since I read this one, so I'm just trying to quickly refresh my mind on it.

Q. Fine. Can you just confirm with me that is a randomized trial with one group having native repair while the other group received mesh called Gynemesh PS?

A. It'll take me just a moment.
Q. Sure.
A. This one is a little further down between my permanent between-the-ears database.
(Reviewing document.)
Q. While you're reviewing that, Doctor, my question was, simply, can you confirm that it's a randomized trial?
A. I don't like to stop at the word "methods" because sometimes when I read further, I realize it wasn't truly randomized even though it was the intent of the study. So that's -- because most of these studies, I've covered just recently in my preparation for this deposition. This one is an older study that is -- I have read, but it's been a long time. So I just want to quickly look at it again.
Q. All right. I apologize for interrupting you.
A. No, that's okay, sir.
(Reviewing document.)

Yes, it was a randomized controlled study.
Q. All right. Was it peer-reviewed, sir?
A. I'm not familiar with Arch Gynecology Obstetrics. I don't know if it's a peer-reviewed journal.
Q. Any reason to believe it's not?
MR. THORNBURGH: Objection.
THE WITNESS: No reason either way. Could be -- no reason to believe it is.
BY MR. TOMASELLI:
Q. Okay.
A. If you represent that it is, I can accept that for today.
MR. THORNBURGH: Just for the record, the journal address is in Dubai.
THE WITNESS: They may have a peer-reviewed journal.
MR. THORNBURGH: I'm not saying it's not. Just for the

record, it's Dubai.
MR. TOMASELLI: Thanks, Dan.
THE WITNESS: They have excellent shawarma in Dubai.
(Exhibit Number 21, Article Titled "Three-Year Outcomes of Vaginal Mesh for Prolapse, A Randomized Controlled Trial," by Gutman, et al., was marked for identification.)
BY MR. TOMASELLI:
Q. Dr. Zipper, I'm handing you what I've marked as Deposition Exhibit Number 21, sir, and this is a study that was published by Gutman and others.
Do you see that, sir?
A. Yes.
Q. Can you confirm that this is a randomized trial comparing Prolift to native repair? In fact, it's an update from the Iglesia paper. True?
MR. THORNBURGH: Objection.
THE WITNESS: No, I can't confirm that yet. I'll have to

look at it.
BY MR. TOMASELLI:
Q. Okay. Please do.
A. (Reviewing document.)
Yes. This thing's also a bit more fuzzy in my mind. But my recollection of this study is that it is a randomized -- it is a continuation of the Iglesia study, which confirmed that there was absolutely no benefit from the Prolift over native tissue surgery.
Q. All right. My question to you, Dr. Zipper, is: Is this paper, published in 2013 by Gutman and others, a randomized comparison between Prolift and a native tissue repair?
A. This --
MR. THORNBURGH: Objection.
THE WITNESS: -- three-year follow-up on the Iglesia and Sokol study, which shows absolutely no significant benefit of Prolift over native tissue surgery appears to be in a randomized -- a

continuation of the randomized control trial published in a peer-review journal.
BY MR. TOMASELLI:
Q. So you can confirm that Gutman 2013 is peer-reviewed?
A. The Journal of Obstetrics & Gynecology is a peer-reviewed journal.
I ordered Chinese for everyone. It should be here pretty soon.
Q. Seriously?
A. No, not seriously. Sorry. That was cruel. Actually, if you knew how bad the Chinese was in Melbourne, you'd be happy I didn't.
Q. Fair enough.
(Exhibit Number 22, Article Titled "Transvaginal cystocele repair using tension-free polypropylene mesh at the time of sacrospinous colpopexy for advanced uterovaginal prolapse: a prospective randomised study," by Qatawneh, et al., was marked for

identification.)
BY MR. TOMASELLI:
Q. Doctor, I'm handing you what I've marked as Deposition Exhibit Number 22, which is a study by Qatawneh and others published in Gynecologic Surgery in 2013.
Do you see that?
A. 2000 -- oh, you're on -- yes. Exhibit Number 22?
Q. Yeah. It's published in paper in 2013, published online in 2012, if that's the hesitation you had.
A. No, no. I agree.
Q. Okay. And can you confirm that this is a randomized comparison of patients undergoing a native surgery versus patients undergoing a mesh surgery with Gynemesh PS?
MR. THORNBURGH: Objection.
THE WITNESS: I'll need just a moment, and I'll get back to you.
///

BY MR. TOMASELLI:
Q. Okay.
A. (Reviewing document.)
Can you restate your question?
Q. Sure.
Can you confirm that Deposition Exhibit Number 22, the study by Qatawneh and others, published in 2013 in paper and 2012 online, is a randomized comparison between native tissue repair and Gynemesh PS?
MR. THORNBURGH: Objection.
THE WITNESS: No.
BY MR. TOMASELLI:
Q. Why can you not confirm that?
A. Because that's not what it's comparing.
Q. What is it comparing?
A. This is a study comparing the use of Gynemesh PS combined with sacrospinous ligament fixation, so a combination of native tissue surgery and

mesh with Gynemesh PS, to native tissue -- the same native tissue surgery, the same sacrospinous colpopexy with native tissue alone. So native tissue with sacrospinous to anterior mesh with Gynemesh to sacrospinous, so it's comparing a combination of native tissue surgery and Gynemesh PS to native tissue surgery alone with that same sacrospinous ligament fixation.
And this is -- so that's what it does. That's what it's a comparison of in a randomized controlled trial, and it's a methodology that was never taught in any of the labeling of any of the Ethicon products.
Q. Okay. So if I can just understand what you said, Dr. Zipper, this is a randomized comparison where everyone in the trial received sacrospinous ligament fixation, and half the group received a other native repair and the other half of the group received Gynemesh PS?

A. Self-tailored Gynemesh PS.
Q. Okay. Is that study peer-reviewed, sir?
A. I believe it is.
(Exhibit Number 23, Article Titled "Comparison of vaginal mesh repair with sacrospinous vaginal colpopexy in the management of vaginal vault prolapse after hysterectomy in patients with levator ani avulsion: a randomized controlled trial," By Svabik, et al., was marked for identification.)
BY MR. TOMASELLI:
Q. Doctor, I'm going to hand you what I've marked as Deposition Exhibit Number 23. And this is a study by Svabik, S-V-A-B-I-K, and others, published in 2014.
Do you see that?
A. Yes.
Q. Is this a randomized controlled trial comparing native surgery

to Prolift?
A. My recollection of this trial is that this was a unique trial that the principal investigator felt it was unethical to enroll all patients because of the risks associated with mesh, so he limited it to patients with some unique 3-D and 4-D ultrasound findings. And it is my recollection that it is a randomized controlled trial where they found a massive de novo SUI rate, I think 36 percent with the Prolift versus around 9 percent with native tissue and twice the dyspareunia rate, is my recollection.
And I do -- yeah. This is a randomized controlled trial. I do not know offhand if Ultrasound Obstet Gynecology is a peer-reviewed journal.
Q. Okay. But we can at least agree that this is a -- that is, Exhibit 23 is a randomized comparison of Prolift and a native tissue repair, correct?

A. I don't think that's precise enough. This is a randomized controlled trial of sacrospinous colpopexy to total Prolift, is my recollection, in a unique subset of a patient population considered to be at very high risk for surgical failure secondary to levator ani avulsion as identified by 3-D and 4-D ultrasound.
Q. Just so I understand some of the data that you just described in this study, can you turn to page 4?
A. Yes.
Q. Do you see down in the right-hand column at the bottom a paragraph that starts "Sexual activity"?
A. Yes.
Q. It says, "Sexual activity was not influenced by the type of surgery. There was no difference in PISQ-12 score between groups both before and after surgery (Tables 1 and 3)."
Do you see where I've read?
A. Yes.
Q. And then it goes on to say,

"At the 1-year follow-up there were two patients with dyspareunia in the Prolift group and one in the SSF group."
Do you see that?
A. I believe that's twice the number of dyspareunia patients. We're talking about trends, as you started doing earlier.
Q. I'm just curious, Doctor, if that was the data that you were referring to?
A. Yes.
Q. Okay.
A. And I believe it says 36 percent de novo SUI rate compared to a 9 percent. So . . .
Q. The two versus one that you just pointed me to in terms of dyspareunia, was that statistically significant in your --
A. I don't recall.
Q. All right. In terms of -- can you turn to the next page just so I can understand some of these charts a

little better? Do you see a Table 3 on the right-hand page over here?
A. Yes.
Q. All right. And that talks about the comparison of the results at one year. Do you see that, sir?
MR. THORNBURGH: Objection.
THE WITNESS: (Reviewing document.)
Yes, I see that table.
BY MR. TOMASELLI:
Q. Okay. And when -- for example, if you go down in Table 3 where it says "Parameter," about six lines down, do you see where it says "total vaginal length"?
A. Yes.
Q. All right. This one actually says "total vaginal length," and other studies there's a report of TVL. Would that be the same thing?
A. Yes.
Q. Okay. And I know you stated that there was a difference in total

vaginal length in the Maher study. Was there a difference in total vaginal length in this study?
A. This study doesn't look like it's reporting the delta, which is the change. So if we don't know what the beginning vaginal length is versus the -- I'd have to look deeper. Maybe it's in here somewhere. I'm not saying it's not there. But just looking at this chart, I can't draw the same conclusion that you are.
Q. Okay. It's up in Table 1. There's preoperative.
A. (Reviewing document.)
Q. And then Table 3 I think is the postoperative. And my question to you is, was there a difference in total vaginal length between the groups in this study?
A. So in this unique subset of patients with 4-D ultrasound evidence of levator ani avulsion, there was not a statistically different significance in

vaginal length between sacrospinous ligament fixation and Prolift.
Q. Okay. And then you mentioned, I think, in one of your answers the results regarding incontinence at the end of one year. Do you remember that?
A. I do.
Q. I think Table 2 has those results for incontinence. Do you see that?
A. Yes.
Q. And was there a statistically significant difference between the groups in terms of incontinence as reported by the authors?
A. It was dramatically higher but not reported as statistically significant. And, Joe, earlier today I cautioned you about the use of trends, and you elected to start a conversation on trends as if they were important. And so I point out here the trend.
Q. Okay. Well, actually,

didn't mean to suggest anything --
A. But also --
Q. -- in my questions but --
A. But we also know from the randomized control data and the Level 1 data, nobody's disputing the fact that transvaginal mesh is associated with a significantly higher incidence of de novo stress urinary incontinence.
And although this one study may have shown a trend and not statistical significance, when you take all these studies and you combine them in a meta-analysis as Cochran did, we find out that transvaginal mesh is associated with a significantly higher incidence of de novo stress urinary incontinence.
(Exhibit Number 24, Article Titled "Multicenter; randomized trial comparing native vaginal tissue repair and synthetic mesh repair for genital prolapse surgical treatment," by da Silveira, et al., was marked

for identification.)
BY MR. TOMASELLI:
Q. I'm going to hand you what I've marked as Deposition Exhibit Number 24, Dr. Zipper, and this is a study by da Silveira, D-A S-I-L-V-E-I-R-A, that was published online and in print in -- sorry. Published online in 2014 and in print in 2015.
Do you see that, sir?
A. Yes.
Q. All right. And can you confirm that this is a randomized clinical trial between a native tissue repair and Prolift?
A. Yes.
Q. And was this peer-reviewed, sir?
A. Yes.
(Exhibit Number 25, IUGA Resonation Abstract Titled "Long-term Follow-up (7 years) of a Randomized Controlled Trial:

Trocar-Guided Mesh Compared With Conventional Vaginal Repair in Recurrent Pelvic Organ Prolapse," by Damoiseaux, et al., Presented 6/11/15, was marked for identification.)
BY MR. TOMASELLI:
Q. Doctor, I'm going to hand you what I've marked as Deposition Exhibit Number 25, which is a presentation abstract in 2015 from an author, Damoiseaux and others, spelled D-A-M-O-I-S-E-A-U-X.
Do you see that?
A. Yes.
Q. Do you see the title of the presentation is "Long-Term Follow-Up (7 Years) of a Randomized Controlled Trial: Trocar-Guided Mesh Compared With Conventional Vaginal Repair and Recurrent Pelvic Organ Prolapse."
Do you see that?
MR. THORNBURGH: Objection.
THE WITNESS: Yes.

MR. THORNBURGH: Do you want me to tell you what the objection is?
MR. TOMASELLI: The title? Yeah. Sure.
MR. THORNBURGH: The -- we've gone through a bunch of these peer-reviewed publications where you suggest are peer-reviewed publications, and here we've got an abstract which provides some incomplete information.
MR. TOMASELLI: Okay. I just asked the title, if you look back at my question.
MR. THORNBURGH: I think the way your question reads and the context of the line of questioning that you've been asking creates a misperception about this document.
MR. TOMASELLI: Okay. Well, I -- I think I said it was an abstract, but if I failed to say

that it was an abstract, I'm very, very sorry.
BY MR. TOMASELLI:
Q. Doctor --
A. I have a vague recollection of this study, but I would need to review this. As noted, it's an abstract, but I do believe this is an abstract that not only showed that there was no significant benefit of using mesh versus native tissue, but I believe this is the abstract that showed that there's more harm than good and that mesh should not be considered and people should look to avoid mesh surgery.
But I'd have to revisit this. It's been a while.
Q. Okay. Can you confirm that this abstract is the -- well, let me start this way: Dr. Zipper, can you confirm that Deposition Exhibit Number 25 is an abstract reporting the long-term seven-year data of a randomized controlled trial comparing Prolift to a

native repair?
A. This is what it states. I confirm that.
Q. Are you aware of any publication that is a manuscript instead of an abstract related to these results for seven years?
A. I am not.
Q. And this abstract was apparently presented at the International Urogynecologic Association meeting in 2015.
Do you see that?
A. Yes.
Q. Okay. Dr. Zipper, we've been through a variety of randomized comparisons between Prolift or Gynemesh PS and native surgery of one type or the other.
Are you aware, sitting here today, of any other randomized comparisons of Prolift compared to native tissue repairs?
A. We'd have to go through --

MR. THORNBURGH: Objection.
THE WITNESS: We have to -- I've read so many articles, we'd have -- I would start then by -- maybe together you and I can go through my opinion, which is here, and compare the -- the numerous articles that I review in my opinion to the ones that you presented and see if any were excluded.
BY MR. TOMASELLI:
Q. Okay. And I'm not -- I'm not thinking that I have that much time to go through your whole 200-page report and see if we can match these up, and I frankly did the best I could to pull out the randomized comparisons. And I'm just asking you, sitting here today -- and I don't know if that's unfair or not, but sitting here today, are there any other randomized comparisons coming to your mind that I did not pull out?
MR. THORNBURGH: Objection.

THE WITNESS: I would -- the vast majority of meaningful literature of both literature cited by plaintiff and defense is discussed and analyzed in my expert report, the majority of which includes what you have handed me today, and is consistent with my opinion of the material and methodologic defects of the Prolift and the Prosima device.
BY MR. TOMASELLI:
Q. When authors report a measure of PISQ-12, do you know what I'm talking about?
A. The PISQ-12.
Q. What is the PISQ-12?
A. It's a validated questionnaire that relates to pelvic organ prolapse symptoms.
Q. Does it relate to sexual symptoms?
A. I believe there are one or two questions in there that relate to

sexual symptoms, maybe even more. There may be more.
Q. When authors refer to a PFIQ scale, do you -- does that make sense to you?
A. The PISQ?
Q. The PFIQ.
A. I'm -- I can't recite that questionnaire. I'd have to look at it.
Q. Okay. What about the PFDI schedule?
A. Yeah. Yes, I'm familiar with it.
Q. All right. And what does the PFDI schedule or --
A. The inventory? I can't -- I also can't list out the inventory to you.
Q. Okay. And sometimes authors will refer to PGI. Do you know what that stands for? Is that Patient Global Improvement?
A. Yes.
Q. All right.
A. Thanks for the leg up.

more (i.e. leading edge of any compartment and thus not limited to treated compartment) or repeat prolapse surgery, the 'failure rate' in the conventional group would have been 66% (56 of 84 patients) and 49% (41 of 83 patients) in the tension-free vaginal mesh group," a P-value of .03.

Do you see that, sir?

A. Give me a moment.

(Reviewing document.)

I believe when they went on to reanalyze their data, they found that the -- and looked at not just the treated compartment but looked at all compartments, they found a four to fivefold higher rate of prolapse beyond the hymenal ring in the mesh group versus the native tissue group.

So this is one of the things we talked about with Withagen. Withagen is one -- the Withagen study shows how bad the untreated compartment failure is, and you can't ignore that.

So at the end of the day, the overall failure rate, when you consider untreated compartment, is dramatically higher with Prolift compared to native tissue. Withagen demonstrates that. When Withagen looks in his next paper and reports on it, all compartments, not just the treated compartment failure, even use the hymenal ring, Prolift performs four times worse than native tissue.

And this is something that's been shown over and over again by other authors.

Q. Dr. Zipper, is your interpretation of that comparison that we just read, is your interpretation that, when you consider all compartment failure between the groups, that mesh fared worse?

A. Remember I said I wouldn't look at this one Withagen paper in isolation, because those authors continue to report on that -- on that data set,

and when they went pack and report on that data set including the untreated compartment failure, they realized that the mesh performed very poorly in comparison. The Prolift performed very poorly in comparison to the native tissue surgery, secondary to the incredibly high incidence of untreated compartment failure, as over 50 percent in the anterior compartment, meaning when you treat the anterior compartment with Prolift and not the posterior compartment, Withagen found a 50 percent incidence -- 53 percent incidence of untreated compartment failure.

And when Withagen went back and looked at that, the Withagen group said, "Wow, when we look at all the compartments, this is a bust. The Prolift ends up with a much higher failure rate compared to the native tissue surgery, even when we look at the hymenal ring as the endpoint and not Stage 0 and Stage 1 prolapse."

Q. Doctor, you have some opinions in your reports regarding the information warnings for Prolift and Prosima. And you say that those are inadequate, correct?

MR. THORNBURGH: Objection.

THE WITNESS: Yes.

BY MR. TOMASELLI:

Q. All right. And when do you believe you became an expert in warnings, sir?

A. I am -- I represent myself as an industry expert in labels and safety and -- and safety and efficacy analysis and validation. And in the last two years alone, I've been hired at the executive level to create labels, labeling guidelines, safety and efficacy plans for medical devices from companies that had been publicly traded in the past that have multi-million dollar valuations.

My expertise in industry standards, including labeling, safety and

safety and efficacy; providing guidance to other people's device companies, to my own device companies; educating people from device companies.

I take those standards, worldwide standards that I've become familiar with, which I've been hired to work with and help device companies for, and I apply them to the companies based on their internal documents, based on the scientific literature, based on my knowledge, training, and experience, and either they pass the litmus test or they don't.

Q. And so if I understand your answer there, you would consider that this expertise on warnings goes back many years?

A. It's developed as a process over the course of the last 20 years.

Q. All right.

A. And I've become stronger and stronger to where, over the last couple years, I have become recognized and

sought after by fantastic young device companies with very exciting technology at various stages of development.

Q. Right. When you say the last couple years, 2013, 2014?

A. I've been doing this for way longer than that.

Q. Okay. Fair enough.

And when do you believe -- maybe it's the same answer, but when do you believe you became an expert on what information needs to go into the IFU? Would the same answer apply?

A. It's an evolving process, but certainly I've been doing it for others for eight to ten years.

Q. Okay.

A. Doing it for myself for a little bit less than that, and over the last two years have worked more extensively as a consultant providing this type of guidance and have taken on a role as president and COO of a formerly publicly traded company with a multi --

probably at this point a $25 million valuation to supervise their labeling, their safety and efficacy pathways, and regulatory -- I'm sorry. Not regulatory -- safety and efficacy pathways and research and development, is what I meant to say.

And just two weeks ago, another device company that exists outside the medical space has hired me for the same purposes, to help them with their labeling, to help them with their safety and efficacy, and bring them to market.

Q. You discuss some of the medical regulations for devices in your reports, and I think you just referenced them.

A. No, I actually I meant to say research and development. I corrected that.

Q. All right. In terms of the regulations pertaining to mesh and medical devices, when do you believe that

you became an expert in those FDA regulations --

MR. THORNBURGH: Objection.

BY MR. TOMASELLI:

Q. -- that you mention in your reports?

MR. THORNBURGH: Objection.

THE WITNESS: I --

BY MR. TOMASELLI:

Q. Would it be the same answer, that it's many years?

A. My -- I represent myself as an expert in industry standards, and I gave you a narrative a moment ago describing how I developed as an expert or how I came to be intimately familiar and have expertise in the standards that pertain to labeling and safety and efficacy.

Now, those standards have been codified by the ISO, by the FDA, utilized by the Committee Européene, which is the CE that you think of.

But these are just different

codifications of the standards which have existed forever. And if you have -- if you're familiar with the basic guidelines required to be a good, ethical human being and perform your fiduciary duties to a company, you coincidently will typically be in alignment with guidance from those various agencies, including the ISO and the FDA, and, in doing those, often be ready to have notified in body state that you meet the CE guidelines or needs, and does.

So to answer -- and in final, I've been familiar with the FDA guidelines for many years, but more crystalized to the specific codes and the minutia of it over the last few years.

Q. All right. And probably, I guess just to put a time point on that, going to the early 2010s or so?

A. I don't know.

MR. THORNBURGH: Objection.

BY MR. TOMASELLI:

Q. All right. When do you

believe that you became an expert in the regulatory process --

MR. THORNBURGH: Objection.

BY MR. TOMASELLI:

Q. -- for mesh devices?

A. I don't know.

Q. Is that something you've been involved with for many years?

MR. THORNBURGH: Objection.

THE WITNESS: Once again --

BY MR. TOMASELLI:

Q. I mean, kind of the same answers?

A. -- I want to be clear that I represent myself as an industry expert and an industry standard expert, which is not as narrow-scoped as what you're describing, if you're suggesting that a regulator expert is somebody who specifically has expertise in the FDA code. Now --

Q. So I didn't -- I didn't mean to suggest one way or the other, I don't think.

A. So --

Q. What I was -- here's my question.

A. I need clarification then. When you say "regulatory," what do you mean?

Q. Sure. Here's my questions. You mentioned a lot of FDA regulation in your Prolift report, correct?

A. Because a massive portion of the Prolift internal database on the Crivella database involves a very lengthy and bizarre regulatory process where they came to market with a device that was never cleared for the regulatory process.

And what's most important to me about that plethora of internal documentation is not some -- not so much the deceptive nature of the interactions between Ethicon and the FDA and how, in doing so, they created misbranding. To a greater extent, it's the -- it is a black-and-white, written acknowledgment about what Ethicon knew about their

product in their interactions with the FDA. They're admitting everything they know about their product, including a lot of misleading statements.

And admitting all that has nothing to do with the FDA. They're demonstrating that they have violated the standards, worldwide standards, of labeling, safety and efficacy that have nothing to do with the FDA codes.

Q. And when did you become -- or when do you believe you became an expert in that regulatory process that you just described?

MR. THORNBURGH: Objection.

THE WITNESS: Which process are you talking about?

BY MR. TOMASELLI:

Q. Well, you mentioned a regulatory process regarding the interactions with the FDA. And so I'm wondering when you became an expert in that.

MR. THORNBURGH: Objection.

THE WITNESS: You'd have to ask the people that hired me when they feel I became an expert.

BY MR. TOMASELLI:

Q. Okay. And can you take me back and just give me a time frame of when you've been hired to do that?

A. I've worked with device companies that overlapped labeling where I was challenged with editing and making labeling suggestions for many years, dating back to probably the mid-2000s.

Then I was required to create regulatory-pathway opinions for my own companies since probably 2010ish, and over the last few years for other people's companies.

Q. Okay. I do want to mark, as I mentioned you to you earlier, some data regarding Prosima. Do you want to take a quick break, and maybe it'll make it quicker.

MR. THORNBURGH: How much time is left?

MR. TOMASELLI: 1:18:00.

THE WITNESS: I would have guessed 49.

MR. TOMASELLI: Can we take a quick break?

MR. THORNBURGH: Yeah. We can take a quick break. No problem.

(Break taken from 1:33 p.m. to 1:41 p.m.)

BY MR. TOMASELLI:

Q. Dr. Zipper, are you ready to proceed?

A. Yes, I am.

Q. Great. I want to talk to you -- go back to the Prosima device, if we can for a little bit.

Would you agree that there is less dissection of tissue for the Prosima device compared to the Prolift device?

A. No.

Q. Would you agree that there are no arms in the Prosima that are

pulled through muscle bodies or ligament structures?

A. Yes.

Q. Would you agree that with respect to Prosima there is no passage of the arms through tissue with trocars?

A. Yes.

Q. Would you agree that the mesh was smaller --

A. I'd like to add to that comment. If the procedure is performed uneventfully, there is no passage of the mesh through muscles with trocars, but secondary to the instrumentation and arms associated with the instrumentation, the possibility of accidentally placing the mesh through muscle bodies exists.

Q. I suppose as devised, the Prosima does not encompass passage of the arms through tissue with the use of trocars?

A. Yes.

Q. Would you agree that the mesh, in terms of Prosima, was smaller in

size than the Prolift mesh?

A. Yes.

Q. Would you agree that Prosima was commonly referred to as a nonanchored mesh?

A. I'm not familiar with that rubric.

Q. Would you agree that the Prosima was not permanently sutured to a muscle or ligament?

A. I would agree that that was not part of the labeling.

Q. The vaginal support device, with respect to the Prosima, the predicate for that device was called a Silimed vaginal stent; is that right?

A. I don't think it was silly. But yes Silimed vaginal stent was one of the claimed predicates for the Prosima device.

Q. And was the Silimed stent made of silicone?

A. Yes.

Q. Was it placed in the vagina?

things? I think you said earlier that you would agree that the Prosima device was cleared by the FDA, I think you said, in early 2007; is that right?

MR. THORNBURGH: Objection.

THE WITNESS: The FDA makes it clear in their guidance that it is the responsibility -- no. I'm sorry. The word is "relies." It relies on the manufacturer to provide accurate information about the predicate devices, and it uses that in addition to their own files.

So in the later part of 2006, Ethicon submitted their regulatory file to the FDA, and a few months later it went through the process and received clearance, I believe in the early part of 2007, and the FDA did their evaluation based on the information provided by Ethicon, including the fact that they

stated that their VSD was equivalent to the Silimed, but yet in another document right in their database they state, word for word, "we have a different intended use."

And by definition, if you have a different intended use, you're not substantially equivalent.

BY MR. TOMASELLI:

Q. Dr. Zipper, are you second-guessing the judgment of the FDA in clearing Prosima?

MR. THORNBURGH: Objection.

THE WITNESS: I'm in no way second-guessing anyone. I'm stating the obvious. The obvious is that the FDA -- and this is a known fact -- relies on the device companies. The FDA does not represent themselves as experts in vaginal surgery, heart surgery, lung surgery. They do not

represent or suggest that they understand a specific device better than a manufacturer.

And that's why they do have to rely heavily on the manufacturer. And if the manufacturer is not completely forthcoming and does not provide all the material facts, then the FDA doesn't have that at their disposal to make a decision.

So what I am stating is that the Prosima VSD was in no way, shape, or form substantially equivalent to the Silimed vaginal stent, and Ethicon recognized that and admitted it.

BY MR. TOMASELLI:

Q. All right. And the reason that you know what Ethicon --

A. Because they wrote it.

Q. Because they wrote it. So it's in their documents?

A. It's in their documents, and

I believe it's in my report.

Q. Okay.

A. With a citation.

Q. All right. We talked earlier about a study by Carey in 2009 that you referred to as a --

A. Talking about the one-year study or the randomized controlled study?

Q. The randomized controlled study, the one that we marked.

A. Okay.

Q. We talked about the Carey 2009 paper, and you referred to that as a Prosima study.

Do you remember that?

A. The randomized controlled trial by Carey was Prosima without the VSD. I went back and I corrected that. And with another exception is that it also used a shape of mesh that was never sold with Prosima.

(Exhibit Number 26, Article Titled "Vaginal surgery for pelvic organ prolapse using mesh and a

the Chinese Journal of Obstetrics & Gynecology in 2012 that is several pages long, probably six pages long, all in Chinese, with one paragraph in English, and the word "Prosima" does appear.

BY MR. TOMASELLI:

Q. Doctor, we talked about the use of robots in abdominal sacrocolpopexy a little bit before, correct?

A. Yes.

Q. In terms of the mesh that's in the shape of the Y that extends from the sacrum down to the vagina -- are you with me in that visualization?

A. The hand movement's helping.

Q. Okay. In terms of the flaps, the two Y flaps, how long down the anterior and posterior walls of the vagina do those Ys go?

A. Surgeon-specific.

Q. Okay.

A. Patient-specific.

Q. Can you give me a range?

MR. THORNBURGH: Objection.

BY MR. TOMASELLI:

Q. What do you do?

A. I base it upon the patient, their symptoms, whether they're sexually active, not sexually active, unfortunately how severe their scarring and fibrosis is from their previous Prolift or other vaginal mesh.

A very, very large number of the patients that we perform these surgeries on are patients that have contracted anterior and/or posterior mesh, including Prolift, which absolutely affects how we do the sacrocolpopexy procedure.

I do tend to -- there are times that I limit my anterior and posterior leaves of the Y to the proximal portion of the vagina. There are times that I provide a more comprehensive dissection of the anterior and posterior compartment with larger Y segments.

Q. All right. And can you give me the range that you just described in centimeters?

A. No.

MR. THORNBURGH: Objection.

THE WITNESS: Because it varies on the vaginal length, right. So many of these women who have severe vaginal -- I'm sorry -- who have severe contraction on transvaginal mesh have a loss of vaginal length. And because of -- and those patients, 3 centimeters of Y might represent more than half of their vaginal length. And there could be a woman who's never had -- who's had only a hysterectomy who has vaginal length of 12 centimeters. And I may be able to put 5 centimeters on her and only have half the vaginal length.

So it's very patient-specific, often related to

the previous mesh surgery and related complications.

BY MR. TOMASELLI:

Q. All right. You stated that you use a Y-mesh called Alyte, correct?

A. I -- that may not be the pronunciation, but yes.

Q. It is Alyte Y?

A. It's -- yes, it's either Alyte or Alyte, yes.

Q. All right. And this is manufactured and sold by a company called Bard, correct?

A. Yes.

Q. Is it made of polypropylene?

A. Yes.

Q. Have you seen -- withdrawn. Is it a macroporous lightweight mesh?

A. It is a --

MR. THORNBURGH: Objection.

THE WITNESS: -- large-pore lightweight mesh.

///

BY MR. TOMASELLI:
Q. And do you know the weight in grams per meters squared?
MR. THORNBURGH: Objection.
THE WITNESS: My recollection is that it is in the -- it's -- I'm not comfortable giving you an exact number, but it's my recollection it's either in the -- it's in the low 20s or less.
BY MR. TOMASELLI:
Q. Do you know the pore size in millimeters?
A. It -- I believe the weight and the pore size varies between the arms and the sacral arm of the mesh. Let's be clear that the material defects associated with polypropylene mesh, although they continue to exist in the use for sacrocolpopexy, the consequences are dramatically different and much less severe secondary to the fixation points and the dissection required to place the

material.
Q. Do you know the pore size of Alyte Y in millimeters?
A. I can't give you the exact number today. It is something I have been familiar with in the past and can easily be familiar with again.
Q. When did you start using Alyte Y-Mesh in ASC repair?
A. I don't recall.
Q. Do you know how it was cleared or approved by the FDA, if at all?
MR. THORNBURGH: Objection.
THE WITNESS: It is cleared. I don't remember what the exact nomenclature of the indication is.
BY MR. TOMASELLI:
Q. Do you know when it was cleared by the FDA?
A. I do not.
Q. Do you know if there were any long-term randomized clinical trials at the time of clearance by the FDA?

MR. THORNBURGH: Objection.
THE WITNESS: What would you consider long-term?
BY MR. TOMASELLI:
Q. Let me modify the question. Are you aware of any randomized clinical trials with Alyte Y-Mesh at the time of approval or at the time of clearance by the FDA?
A. I'm mostly aware --
MR. THORNBURGH: Objection.
THE WITNESS: -- of the fact that there is an extended database of the safety and efficacy of abdominal sacrocolpopexy as well as the relevant complications associated with abdominal sacrocolpopexy, and there is no particular large-pore, lightweight mesh that I believe is superior or inferior when it comes to the treatment of abdominal sacrocolpopexy. And although the material is

effective and has significant complications, the risk/benefit ratio supports the use of lightweight, large-pore polypropylene mesh in the treatment of significant pelvic organ prolapse until such a time that a safer, more effective alternative is available.
BY MR. TOMASELLI:
Q. Is Gynemesh PS included in your last answer?
MR. THORNBURGH: Objection.
THE WITNESS: The material defects -- actually, the answer is no.
BY MR. TOMASELLI:
Q. Okay.
A. Because -- I'd like to finish that. Gynemesh PS is perhaps the only mesh I'm aware of that has been shown to be uniquely -- have a uniquely negative impact on tissue. Gynemesh PS has been shown to actually eat away

tissue, to be catabolic to tissue. It has been shown to dramatically decrease collagen, dramatically decrease elastin. It has been shown to cause an 80 percent decrease in the contraction of the vagina when used in sacrocolpopexy.

So it is the one mesh, Gynemesh PS, that has been shown to be inferior to other meshes it's been compared to and dangerous in comparison. So I disagree with your statement.

Q. I just want this particular question: Are you aware of any randomized clinical trial with Alyte Y-Mesh at the time of clearance or approval by the FDA?

A. I have not reviewed their regulatory dossier.

Q. Are you aware of any prospective clinical data performed on Alyte Y-Mesh prior to the FDA clearance or approval?

MR. THORNBURGH: Objection.

THE WITNESS: Can you please

restate the question.

BY MR. TOMASELLI:

Q. Sure.

Are you aware of any prospective clinical data performed on Alyte Y-Mesh prior to the clearance or approval of the product?

A. As stated just a few moments ago --

Q. I'm just asking if you're aware.

A. And I'm just giving -- to answer that with a yes-or-no question would be an incomplete answer, and I'm not comfortable giving incomplete answers.

Q. You can say no, and then "This is why it doesn't matter," or --

A. Are you instructing me on how to answer the question, sir?

Q. I'm not.

A. You just did. I don't want to be argumentative.

Q. I'm not try to argue with

you. I'm really not. I just have limited time, and so I just need to know whether you're aware of --

THE WITNESS: Well, can we extend his time by the three minutes it takes me to answer his question?

MR. THORNBURGH: Answer his question. How much time is left on the cross?

MR. TOMASELLI: 17 minutes.

MR. THORNBURGH: Answer the question the best way you have to answer the question.

THE WITNESS: Two wrongs don't make a right, and just because somebody got away with something -- but the bottom line is, before all this happened, we trusted device companies to provide us with adequate information. We believed that device companies did the necessary safety and efficacy testing.

By the time that this became an issue, I already had a history of using the product safely. And as stated earlier, the use of polypropylene mesh for abdominal sacrocolpopexy, with the exception of Gynemesh PS, has a history that demonstrates that the risk/benefit analysis is meritorious compared to other alternatives; and, therefore, although companies may not have done the randomized controlled trials that they should have done, the experiment has happened in realtime, and it's provided the necessary realtime data.

BY MR. TOMASELLI:

Q. Dr. Zipper, do you have or have you reviewed the regulatory file with the FDA and the correspondence between Bard and the FDA regarding the Alyte Y-Mesh?

A. I have not.

Q. Do you have internal memos from Bard regarding the Alyte Y-Mesh?
A. I do not.
Q. Do you have any internal e-mails from Bard regarding the Alyte Y-Mesh?
A. No. In all fairness, I would not look at those unless I was retained as an expert to render an opinion on that.
Q. Have you -- have you asked Bard for their regulatory file, internal memos, or internal e-mails related to the Alyte Y-Mesh?
A. I have not.
Q. Have you asked Bard for any of their risk assessments that have been performed, if any, internally regarding the Alyte Y-Mesh?
A. I have not.
Q. Have you seen the material safety data sheet for the Alyte Y-Mesh, if there is one?
MR. THORNBURGH: Objection.

THE WITNESS: There wouldn't be one for -- I think you understand that, Joe, and I don't mean to sound --
BY MR. TOMASELLI:
Q. Maybe I misspoke.
A. There wouldn't be one for the --
Q. Can I withdraw that?
A. Yes.
Q. With respect to the polypropylene that was used in the Alyte Y-Mesh, have you ever seen an MSDS for that?
MR. THORNBURGH: Objection.
THE WITNESS: No, I have not.
BY MR. TOMASELLI:
Q. All right. Have you seen the Alyte Y-Mesh degrade in any way?
MR. THORNBURGH: Objection.
THE WITNESS: I -- because -- and this is -- I'm glad you bring that up because it

brings back to the forefront of our conversation a very important topic. And I know you have limited time, so I'll be quick.
The material defects -- and I've said this multiple times -- associated with the mesh and the consequences of such are dramatically less with abdominal sacrocolpopexy than transvaginal mesh. We're not dragging it through muscles, attaching it to the pelvic sidewall.
And so when you're asking me if I've seen these things, the only reason the answer is no is because I don't have problems with the product. My patients aren't having complications. I've never had to remove one. I've never had an erosion with one. I've never had vaginal pain or dyspareunia associated with it.
It's not going through the

obturator foramen. It's not going through the obturator muscles. It's not going through the iliococcygeus muscle. It's not going through the obturator muscle. It's not going in and around or near the pudendal nerve. It's not going near the levator ani nerve. It's not causing myofascial pain syndrome.
I'm not having to resect it, and, therefore, I don't have any evidence of these problems because I'm not resecting it.
BY MR. TOMASELLI:
Q. Dr. Zipper, do you know the effective pore size inside the human body of the Alyte Y-Mesh?
MR. THORNBURGH: Objection.
THE WITNESS: No, but I'm very familiar with it with the Ethicon products in that it was -- the arms tend to lose all porosity at physiologic stresses.

REPORTER'S CERTIFICATE

STATE OF FLORIDA
COUNTY OF BREVARD

I, Rhonda Hall-Breuwet, RDR, CRR, LCR, FPR, CLR, NCRA Realtime Systems Administrator, Notary Public, certify that I was authorized to and did stenographically report the deposition of RALPH ZIPPER, MD, FACOG, FPMRS.

I further certify that I am not a relative, employee, attorney, or counsel of any of the parties, nor am I a relative or employee of any of the parties' attorney or counsel connected with the action, nor am I financially interested in the action.

Dated this 4th day of April, 2016.

____
Rhonda Hall-Breuwet, RDR, CRR, LCR, FPR, CLR,
NCRA Realtime Systems Administrator

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ACKNOWLEDGMENT OF DEPONENT

I,____________________, do hereby certify that I have read the foregoing pages, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

____
RALPH ZIPPER, M.D., FACOG, FPMRS DATE

Subscribed and sworn
to before me this
_____ day of ______________, 20____.
My commission expires:______________

____
Notary Public